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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/321,247	CHEN ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-24,29,33,34,38,39*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The priority claim to U.S. provisional patent application 60/032,277 is acknowledged.

Objection to the specification is withdrawn in view of the amendment thereto.

Provisional objection to claims 35-37 is rendered moot by cancellation of the claims.

Rejection of claims 2, 3, 8-12, 18-22 and 34 under 35 USC 112, first paragraph, as lacking adequate written description is withdrawn in view of the amendments to the claims.

Rejection of claims 8-12 under 35 USC 112, second paragraph, as indefinite is withdrawn in view of the amendments to the claims..

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-24, 29, 33, 34, 38 and 39 stand rejected under 35 USC 112, first paragraph, as lacking enablement. In response to the arguments of record, Applicant has amended the claims such that they are now limited to products and methods to be used for ex vivo gene therapy. Applicant again asserts that the specification need not provide a working example of the invention if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. Applicant argues, the fact that experimentation may be complex does not necessarily make it undue if the art typically engages in such experimentation. Applicant contends that the specification is fully enabled for ex vivo gene therapy by incorporation of U.S. Patent application 5,399,346 (hereinafter, Anderson), which discloses many details of the technique of ex vivo gene therapy.

First it must be pointed out that even if one were to assume, arguendo, that the claims are enabled for ex vivo treatment of HIV infection, they would still encompass non-enabled subject matter. Claims 1-7, 13-20 and 38 encompass products and methods of using an expression vector comprising chemokine encoding regions which would not bind to HIV accessory receptors and thus clearly could not be used to treat HIV infection according to the teachings of the specification. As pointed out on page 5 of the previous Office Action, "[t]he specification does not teach any specific diseases associated with any of the numerous other chemokine receptors". Therefore, the skilled artisan must discover how to use the embodiments of the invention that could not be applied to the treatment of HIV infection without any guidance from the specification. Applicant is reminded, "[l]aw requires that disclosure in application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use for themselves" (In re Gardner, Roe and Willey 166 USPQ 138). Applicant's arguments do not address these grounds for rejection; therefore, claims 1-7, 13-20 and 38 are clearly not enabled for their full scope.

With regard to enablement for vectors capable of expressing intrakines that bind to HIV accessory receptors and methods of using said vectors for the ex vivo treatment of HIV, Applicant's arguments have been fully considered but are not found persuasive. Although it is true that working examples are not required for enablement, as pointed out previously, "the enablement rejection set forth in the previous action and maintained herein did not rely solely on the lack of a working example, but relied properly on the analysis of all the Wands factors and is based on the evidence as a whole...in an unpredictable field such as the chemical arts and more specifically, gene therapy, lack of a working example is a factor to be considered" (Non-Final Office Action mailed 23 April 2002). The rejection of record is based on the teachings of the specification and prior art as a whole with one factor being the absence of working examples. It is also true that the fact that experimentation may be complex does not necessarily make it undue if the art typically engages in such experimentation. However, as also pointed out in previous office actions, in vitro findings, such as those to which the instant specification is limited, are very seldom translated into successful gene therapy in spite of the very high level of skill in the art and tremendous effort expended in attempts to treat a variety of diseases using gene therapy techniques. Thus, the translation of promising results obtained in vitro to an even minimally efficacious gene therapy is clearly not routine in the art.

Applicant also argues that the Anderson patent (Id.) incorporated by reference discloses may details of the technique of ex vivo gene therapy, including success using ex vivo gene therapy with lymphocytes and therefore the skilled artisan would believe that they can make and use the claimed invention of the present application. However, the claims of the instant application are to be examined in their own merits notwithstanding the claims of the Anderson patent (In re Giolito, 188 USPQ 645 (1976)). As stated in the previous Office Action "the problem of sustained gene expression remains for ex vivo approaches" (bridging pages 5-6). Given the teachings of Verma et al. and Fox and the arguments of record, the skilled artisan would not consider the instant claims to be enabled for ex vivo gene therapy. Applicant's arguments are not found persuasive individually or as a whole; therefore, the rejection is maintained.

JAMES KETTER
PRIMARY EXAMINER